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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/509,343

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Ryoichi Saitoh

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EXAMINER

DANG, IAN D

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/509,343	<b>Applicant(s)</b> SAITOH ET AL.	
	<b>Examiner</b> IAN DANG	<b>Art Unit</b> 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 10-31 is/are pending in the application.
- 4a) Of the above claim(s) 12-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 10-11, and 31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-6 and 10-31 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/16/2007, 11/09/2007, 10/03/2007</u> .                      | 6) <input type="checkbox"/> Other: ____.                          |



## **DETAILED ACTION**

### ***Status of Application, Amendments and/or Claims***

The amendment of 11/16/2007 has been entered in full. Claims 7-9 have been cancelled and claims 1, 3, 5-6, 11 have been amended. Claims 25-31 have been newly added.

Claims 29 and 30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

This application contains claims 12-24 and 29-30 drawn to an invention nonelected with traverse in the reply filed on 03/05/2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1-6, 10-11, 25-28, and 31 are pending and under examination.

### ***Election/Restrictions***

At page 9 of the response, Applicants argue that there is not indication in Garcia et al. that the cultured Sf9 host cells released a budding virus having an envelope on which the transporter is expressed, much less that the transporter of the viral envelope possessed transporter activity.

Applicant's arguments have been fully considered but are not found persuasive. Although Garcia et al., does not indicate the release of a budding virus having an envelope on which transporter is expressed and the viral enveloped possessing transporter activity, the viral particle disclosed by Garcia et al., would inherently have these characteristics. For instance, the specification teaches that as methods for expressing transporters on viral envelopes, for example, the method of WO98/46777 or Loisel et al. for expressing envelope proteins using

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budding baculoviruses can be used (Loisel, T.P. et al., Nature Biotech. 15: 1300-1304 (1997)) (see page 10, lines 13-16).

Thus the prior art by Garcia et al. meets the limitations disclosed in claim 1 filed 09/28/2004. Thus Group I lacks novelty or inventive step and does not make a contribution over the prior art. Since the first claimed invention has no special technical feature, it cannot share a special technical feature with the other claimed invention.

Under PCR Rule 13.1, the application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept.

The requirement is still deemed proper and is therefore made FINAL. Claims 12-24 and 29-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b).

### **Specification**

The objection to the title has been withdrawn.

### **Claim Objections**

The objections of claims 5 and 11 are withdrawn in view of the amendments made to claims 5 and 11.

### **Rejections Withdrawn**

#### ***35 USC § 112, First paragraph (Written Description)***

Applicant's response and arguments filed on 11/16/2007 have overcome the rejection of claims 1-11 under 35 USC 112, First paragraph (Written Description). The rejection of claims 1-11 under 35 USC 112, First paragraph (Written Description) has been withdrawn.

***35 USC § 112, First paragraph (Enablement)***

Applicant's response and arguments filed on 11/16/2007 have overcome the rejection of claims 1-11 under 35 USC 112, First paragraph (Enablement). The rejection of claims 1-11 under 35 USC 112, First paragraph (Enablement) has been withdrawn.

***35 USC § 102***

Applicant's response, arguments, amendments made to claims 1 and 6, and cancellation of claims 7-9 filed on 11/16/2007 have overcome the rejection of claims 1-4 and 6-10 under 35 USC 102(b). The reference of Miyasaka et al., (2001) does not teach the step of harvesting the released virus, wherein the transporter on the envelope of the release virus has transporter activity. The rejection of claims 1-4 and 6-10 under 35 USC 102(b) has been withdrawn.

***35 USC § 102***

Applicant's response, arguments, and amendments made to claim 1 filed on 11/16/2007 have overcome the rejection of claims 5 and 11 under 35 USC 103(a). The reference of Miyasaka et al., (2001) does not teach the step of harvesting the released virus, wherein the transporter on the envelope of the release virus has transporter activity. The rejection of claims 5 and 11 under 35 USC 103(a) has been withdrawn.

***New ground of Rejection***

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6, 10-11, 25-28, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miyasaka et al. (2001, Protein Expression and Purification, Volume 23, pages 389-397, cited in the last Office action) in view of Loisel et al., (1997, Nature Biotechnology, Volume 15, pages 1300-1304, cited in the IDS mailed March 09, 2005 as reference BF) and Hsu et al., (1998, Pharmaceutical Research, Volume 15, Issue 9, page 1376-1380, cited in the last Office action).

Miyasaka et al. teach a method of expressing the peptide taurine transporter wherein the method comprises culturing Sf9 cells with the recombinant virus baculovirus that comprises the taurine transporter gene (page 389, abstract) and harvesting the released virus from plated Sf9 cells (page 390, right column, last paragraph). In addition, the mammal taurine transporter is derived from a non-virus and is a peptide transporter (page 389, right column, 1<sup>st</sup> paragraph). However, Miyasaka et al. does not teach the expression of the transporter on the envelope of a

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budding virus released from the host cell, a virus with taurine transporter activity, and the oligotransporter PeptT1.

Loisel et al teach a method comprising culturing a host cell (the Sf9 insect cell) that is infected with the budding virus baculovirus comprising a gene recombinantly encoding beta-adrenergic receptors. In addition, Loisel et al. teach the expression of the adrenergic receptor on the extracellular surface of virions of baculovirus that are released from the host cell and the harvesting the release virus, wherein the receptor on the envelope of the release virus has adrenergic activity (page 1300, left column, 2nd paragraph).

Hsu et al teach the method of the expression of the oligotransporter PeptT1 using PeptT1 using an adenoviral vector.

Thus, it would be obvious for one skilled in the art to modify the method for expressing an adrenergic receptor, wherein the method comprises culturing a host infected cell with a recombinant virus that comprises a gene encoding the receptor, expressing the receptor on the envelope of a budding virus released from the host as taught by the peptide taurine transporter of Miyasaka et al. and using the transporter, PepT1, as taught by Hsu et al. (1996). One of ordinary skill in the art at the time the invention was made would be motivated to express Pept1 in baculovirus because extracellular virions (ECV) of baculovirus may be used to study plasma membrane-restricted processes (Loisel et al.; page 1303, right column, 1st paragraph). One skilled in the art would have expected success because the PepT1 gene has been expressed successfully in a viral vector and numerous other membrane transporters have already been expressed in Sf9 cells using the baculovirus system at the time the invention was made. Accordingly, the invention taken as a whole is prima facie obvious.

## Conclusion



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No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

### Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IAN DANG whose telephone number is (571)272-5014. The examiner can normally be reached on Monday-Friday from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ian Dang  
Patent Examiner  
Art Unit 1647  
January 25, 2008

/Manjunath N. Rao, /  
Supervisory Patent Examiner, Art Unit 1647